UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,987	10/23/2003	Steven M. Griffiths	11201-728-999	4737

20583 7590 10/27/2008

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
MACNEILL, ELIZABETH	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
10/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,987	GRIFFITHS ET AL.	
	Examiner	Art Unit	
	ELIZABETH R. MACNEILL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 29,31, 33, 34,45,47,49,50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg (US 6,807,797) in view of Szapiro et al (US 5,785,683)

Forsberg discloses that "A typical dual-chamber syringe and a process for automated manufacture of prefilled such syringes is disclosed in Neue Verpackung, No.3, 1988, p. 50-52; Drugs Made in Germany, Vol. 30, Pag. 136-140 (1987); Pharm. Ind. 46, Nr. 10 (1984) p. 1045-1048 and Pharm. Ind. 46, Nr. 3 (1984) p. 317-318. The syringe type ampoule is a dual chamber device with a front bottle type opening for needle attachment, two pistons and an exterior type by-pass for mixing a lyophilized powder in the front chamber with a reconstitution liquid in the rear chamber. The process described includes the main steps of washing and siliconizing the syringe barrels, insertion of multiple barrels in carrier trays, sterilization, introduction of middle piston through barrel rear end, turning the trays upside down, introduction of the powder solution through the front opening, lyophilization to dry powder, closure of front opening while in the lyophilizing chamber, turning of trays, introduction of the reconstitution

liquid through barrel rear end, insertion of rear piston, removal of products from trays and final control and packaging." (Col 2).

Forsberg only discloses the loading procedure for use with mixing syringes where the barrel includes an exterior type by-pass, and therefore does not teach that the chamber has no interior structures, or the seal having a flow path formable there through. Szapiro teaches a well-known type of mixing syringe assembly having a front solid (M), a rear liquid (diluent in 11), a seal (15) having a movable sealing plug (17) operative to move from a sealing position to a by-pass area (Fig 5-7) to open a flow path (22) there through (Fig 6) and a barrel (1) having no interior structures. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the seal and barrel structure of Szapiro with the loading method of Forsberg in order to provide a syringe which is loaded without mixing of the two compartments and which has an extended shelf life (Col 3 line 23).

3. Claims 37-39, 41, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg and Szapiro in view of Odell et al (US 6,263,641). Forsberg teaches the structural limitations of the syringe being formed as shown above, but does not teach the steps of placing the syringe in an aseptic or low-particulate environment. Odell et al teaches a method of making and assembling medical containers involving using sterile environments (for Figures 1-4) and placing the syringes in a low-particulate environment (when filling the dry component, Col 13 lines 33-50), then packaging the syringes in sterile packaging (an aseptic environment).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of assembly of Odell with the device of Forsberg in order to provide a pre-filled syringe which is safe to use and contains uncontaminated medicament.

4. Claims 30 and 40, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg/ Szapiro /Odell in view of Geprags (US 4,781,701).

Forsberg/ Szapiro and Odell do not discuss the structure of the front seal used with their syringe cartridges. Geprags discloses a front syringe barrel seal with a tapered flow path (at 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of assembly of Forsberg/ Szapiro /Odell with the seal of Geprags in order to provide a secure seal of the front end of the syringe (Abstract).

5. Claims 32, 34, 35, 36 and 42,48, 45,47,49,50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg/ Szapiro /Odell in further view of Tanaka et al (US 5,716,339).

Forsberg/ Szapiro and Odell do not disclose filling the rear compartment with a wet medicament before filling the front chamber. Tanaka teaches filling the rear chamber first (Fig 2A) and then filling the front chamber with a dry medication (Fib 2B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Tanaka when filling the syringes in order to prevent mixing of the ingredients.

Response to Arguments

1. Applicant's arguments filed 30 September 2008 have been fully considered but they are not persuasive. Applicant argues that there would be no reason to fill the syringe of Szapiro with the method of Forsberg because the front of Szapiro is much narrower than the back. This would not prevent one of ordinary skill in the art from recognizing that Szapiro is capable of being filled through the front, such as taught by Shields (US 3,807,119). Shields shows filling a powder medicament through the narrowed portion of a syringe (Fig 1 I-K, and claim 4) without regards to the fact that the rear of the syringe is wider. As to the open neck portion, since injection nozzle 5 is tubular it is considered an open neck. As to the tablet, tablets come in many sizes (such as tablets for pets or infants) and one of ordinary skill in the art would recognize that some tablets could be loaded into Szapiro through the front opening.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner MacNeill whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767